

b.) Remarks

Claim 98 is amended in order to more specifically recite the subject matter of the present invention and claims 112-118 are presented in order to more specifically recite various preferred embodiments of the present invention. Claims 99-101 and 106-107 are cancelled as redundant, and claims 102-105 and 109-110 are amended to correct their dependency and/or for better conformity with accepted U.S. practice.

For the Examiner's convenience, the subject matter of amended claim 98 is found within prior claims 100, 101 and 107 and in the specification at page 3, lines 15-23 (as discussed below), and the subject matter of new claims 112-118 is found within prior claims 104, 110 and 111. Accordingly, no new matter has been added.

Claims 98-111 stand rejected under 35 USC 103 as being obvious over Tabor (US Patent No. 6,482,448) in view of Hastings (US2001/0041187), Miller (US Patent No. 6,109,999), Ostlund (US Patent No. 5,550,166) and Shimizu (US Patent No. 6,004,926), each of record.

This rejection is respectfully traversed. However, prior to setting forth their bases for traversal, Applicants would like to briefly discuss the salient features of the present invention and, *inter alia*, its patentable nature over the prior art.

As the Examiner will appreciate, as recited in amended claim 98, the present invention is directed to a method of supplementing a human diet to enhance muscle size and strength by orally administering effective amounts of protein selected from whey protein, whey peptides, milk protein, casein, albumin and soy, together with a compound that mimics (or enhances) insulin activity selected from inositol or a specific inositol derivative, and creatine or a compound which increases nitric oxide production.

Previously, Applicants argued the present invention provided a synergistic effect over the prior art, e.g., as compared to administering supplements employing only proteins or amino acids, relying in the Declaration under Rule 132 of Dr. Marvin Heuer. Dr. Heuer's Declaration was supported by an abstract to Burke, et al., The Effect of Whey Protein Supplementation With and Without Creatine Monohydrate Combined With Resistance Training on Lean Tissue mass and Muscle Strength, *Int. J. Sport Nut. and Exer. Met.*, Vol. 11 (2001) 349-64. The Burke abstract specifically illustrated results obtained comparing Experiments using the present invention with Comparative Experiments using whey protein.

Nonetheless, on June 28, 2007 the Examiner maintained the rejection since (1) the Heuer Declaration did not directly compare the present invention to the closest prior art, e.g, Burke only compared the present invention to whey protein whereas Tabor teaches soy protein, and (2) the scope of the claims is not commensurate with the showings in the Declaration.

This Request for Continued Examination (RCE) was filed simply in order to afford Applicants with the best opportunity to respond to the Examiner's concerns. These points are, accordingly, addressed below.

I. WHEY VS. SOY PROTEIN

As noted by the Examiner, the cited prior art utilizes soy protein whereas the Burke reference relied upon in the Heuer Declaration relied on showings comparing the present invention to whey protein. It is well-known that compared to other forms of protein, whey is thought to be superior over soy for a variety of reasons, most notably because soy protein contains phytoestrogens which lead to both (i) unwanted decreases in

testosterone, and (ii) increases in the female sex hormone estrogen. For these reasons soy is understood to make it harder to gain muscle. See, e.g., <http://www.bodybuilding.com/fun/drobson71.htm>

Accordingly, in the Heuer Declaration Applicants compared the present invention to whey protein which does not contain phytoestrogens and so is more effective to promote muscle growth. That is to say, the Heuer Declaration compared the present invention to prior art which is closer than the Examiner's own cited art. It is, of course, entirely permissible for Applicants to compare the present invention with compounds even more closely related than those of the prior art. *Ex parte Humber*, 217 USPQ 265 (Pat. Off. Bd. App. 1981).

II. THE CLAIMS ARE NOW COMMENSURATE WITH THE SCOPE OF THE SHOWINGS

As noted above, the method of claim 98 now recites that the dietary supplement orally administered to the human comprises effective amounts of protein selected from whey protein, whey peptides, milk protein, casein, albumin and soy, together with a compound that mimics (or enhances) insulin activity selected from myo-inositol, d-myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol and d-pinitol, and either creatine or a compound that stimulates nitric oxide production.

To complete the record, Applicants enclose herewith (see the accompanying Information Disclosure Statement) a complete copy of the Burke article relied upon in the Heuer Declaration. As noted therein, Burke compared the effects in enhancing muscle strength obtained in supplementing humans with (i) whey protein, (ii) inositol and (iii)

creatine (see table 2) with (i) whey protein and (ii) inositol but (iii) without creatine (see page 351, last paragraph).

In this regard, as noted above, the claimed method also comprises administering to the human a supplement comprising a substance that increases nitric oxide production, since nitric oxide stimulates creatine phosphate biosynthesis and creatine delivery (see specification page 3, lines 15-23). Accordingly, the pending claims either permit coadministering creatine directly or coadministering compounds that stimulate its production *in situ*.

Claims 98, 102-105 and 108-118 are presented for continued prosecution.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

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